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| APPLICATION NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTORNEY DOCKET NO. |
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07/835,964 02/20/92 COATES

J IAF-14

12M1/0424

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EXAMINER

FORD, J

ART UNIT

PAPER NUMBER

1202

DATE MAILED:

04/24/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 1-24-97

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire THREE month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 3, 4, 5, 7, 10, 21 and 22 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 3, 4, 5, 7, 10, 21 and 22 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

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Art Unit: 1202

The claims in the application are claims 3, 4, 5, 7, 10, 21 and 22.

The Finality of the last office action is withdrawn. See Liotta et al, US Patent 5,539,116.

Claims 3, 4, 5, 7, 10, 21 and 22 are rejected under 35 USC 102 and 103 as being unpatentable over Liotta et al (Liotta) U.S. Patent 5,539,116. Note the claims of Liotta are to the (-) enantiomer of BCH-189. Note the structure of BCH 189 is the same as the compound of claim 21, here, just named differently, see col. 5 of Liotta. The methods and pharmaceutical compositions of Liotta would be obvious from the disclosure of Liotta.

Claims 3-5 are rejected under 35 USC 112, 4th paragraph, ~~as~~ being improper dependent claims. Claim 2 indicates it is substantially free of the corresponding (+) enantiomer. A 5% amount, as in claim 3, is not taken to be substantially free of the (+) enantiomer. The claims are rejected as not being within the claim from which it depends.

Claims 3-5 are rejected under 35 USC 112, 2nd paragraph. No indication is given as to how a 5% w/w mixture is obtained. Are these mixtures a result of a process and result, or man-made mixtures?

Claim 18 is rejected under 35 USC 112, 1st and 2nd paragraphs. All viral infections are notoriously resistant to treatment. Hepatitis ^B and HIV treatment could possibly be established, here, but not all virus.

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The expression "including man" is redundant. It is a sub-genus, within a genus, and makes the claim indefinite as to which is being *treated*. See Ex parte Cordova, 10 USPQ 2nd 1949. Examples of "such as" and "particularly" rendering claim indefinite, are given.

Claims 21 and 22 are rejected under 35 USC 112, 1st and 2nd paragraphs, as a result of the pro drug language in these claims. "[O]r a compound which, upon administration to a recipient is capable of providing ----. Does not say what that compound is.

What the pro drug, may be, is an entire other invention, not described or disclosed here.

Claim 21 is rejected under 35 USC 112 1st and 2nd paragraphs, as a result of lack of description and support for the *esters* and *salts* in the claim. Likewise claim 22.

HIV treatment is an extremely sensitive utility. Claims ~~to~~ salts, esters and salts of esters are to unknown compounds with no established utility. Which compounds? § 112, 2nd; *where supported by § 112 / ex. pna.*

Applicant argues p. 3 response of (9/28/95); (-) enantiomer is unobvious over racemic of 5,047,407. However, p. 4 (same response) indicates the (+) and (-) forms of BCH-189 exists. Claim 21, here, is not limited to (-) enantiomer, in one possible reading. Compare with claim 22. The last lines of claim 21

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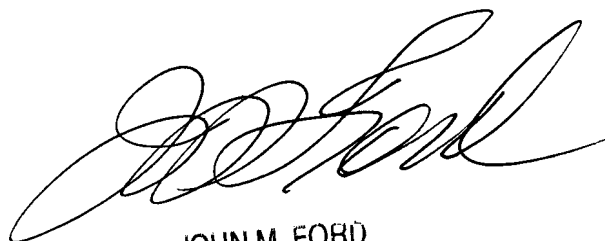
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appear to claim "a compound (unknown) which upon administration to a recipient (pro drug - unknown) is capable of providing ~~+~~ - substantially free of (+) enantiomer (35 USC 112, 1st & 2nd). It is not clear, to what substantially free of the corresponding (+) enantiomer - refers. What is the difference between claims 21 and claim 22? There is no question that the racemate is in claim 10 of U.S. Patent 5,047,407.

Claims 3, 4, 5, 7, 10, 21 and 22 are rejected under 35 USC 102 and 103, as being unpatentable over claim 10 of U.S. Patent 5,047,407. Note the optional isomers are claimed. The (-) enantiomer is resolvable from the (+) racemate, and is included therein; *Eli Lilly* vs. Generic Drug Sales, 169 USPQ 13 and *In re Adamson*, 125 USPQ 233.

J. M. Ford/skf
April 21, 1997



JOHN M. FORD
PRIMARY EXAMINER
GROUP 120 - ART UNIT 1202